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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,136	01/12/2001	Stephen Nuss	990356.ORI	2264

23595 7590 03/25/2004

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	20

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,136	NUSS, STEPHEN	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/8/04 has been entered.

Specification

The disclosure is objected to because of the following informalities: in order to minimize the necessity in the future for converting dimensions given in the English system of measurements to the metric system of measurements when using printed patents as research and prior art search documents, all patent applicants should use the metric (S.I.) units followed by the equivalent English units when describing their inventions in the specification of patent applications. MPEP 608.01 ("Use of Metric System of Measurement in Patent Applications"). All instances of measure found throughout the specification should properly be presented as both metric and English units. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al.

In regards to claims 12 – 27, Cornish et al. discloses a guidewire comprising a titanium alloy core wire having a proximal end and a distal end, the distal end having a smaller diameter than the proximal end; a taper of the diameter between the distal end and the proximal end with the distal end being smaller (Col. 3, line 66 – Col. 4, line 14); a coil (20) attached to the distal end; a distal tip (58) on the distal end; a polymer coating and a hydrophilic coating (Col. 3, lines 50 – 60). Cornish et al. fails to disclose forming the wire from a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight. However, Cornish et al. discloses the wire being formed of "stainless steel or a nickel titanium alloy or a combination thereof, but can also consist of any material that yields the **approximate mechanical properties** of the named metals so long as the material is sufficiently biocompatible" (Col. 3, lines 42 – 47). A titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight is well known for its biocompatibility and its use in the medical arts (See U.S. Patent Application Publication No. 2003/0009215 to Mayer Page 6, [0078] – [0079]; U.S. Patent No. 4,817,600 to Herms et al. Page 4, lines 27 – 35). Applicant has acknowledged that this known titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight has the approximate mechanical properties of stainless steel and nickel titanium. Page 6, lines 17 – 18 acknowledges the titanium molybdenum alloy having "properties between that of stainless steel and NiTi alloys". Additionally, that the claimed alloy is "less springy than NiTi alloys but more springy than stainless steel" and "stiffer than NiTi alloys but not as stiff as stainless steel" (Page 7, lines 18 – 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Cornish et al. to be

formed from a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight in that such an alloy is known to be biocompatible and has properties approximate that of stainless steel and nickel titanium. Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. ***In re Leshin***, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 12 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent Application Publication No. 2003/0009215 to Mayer.

In regards to claims 12 – 27, Cornish et al. discloses a guidewire having a core wire comprising a titanium alloy including nickel having a proximal end and a distal end, the distal end having a smaller diameter than the proximal end; a taper of the diameter between the distal end and the proximal end with the distal end being smaller (Col. 3, line 66 – Col. 4, line 14); a coil (20) attached to the distal end; a distal tip (58) on the distal end; a polymer coating and a hydrophilic coating (Col. 3, lines 50 – 60). Cornish et al. discloses the wire being formed of any suitable material (Col. 3, lines 42 – 47). However, Cornish et al. fails to disclose the titanium alloy being a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight. Mayer discloses a medical device for inserting into body passageways during medical procedures including a titanium molybdenum alloy wire having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight [0078]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the titanium alloy as disclosed by Cornish et al. to include a titanium molybdenum alloy as taught by Mayer in order to avoid undue irritation to patients having a sensitivity to nickel [0079].

Claims 12 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent No. 4,817,600 to Herms et al.

In regards to claims 12 – 27, Cornish et al. discloses a guidewire comprising a core wire having a proximal end and a distal end, the distal end having a smaller diameter than the proximal end; a taper of the diameter between the distal end and the proximal end with the distal end being smaller (Col. 3, line 66 – Col. 4, line 14); a coil (20) attached to the distal end; a distal tip (58) on the distal end; a polymer coating and a hydrophilic coating (Col. 3, lines 50 – 60). Cornish et al. discloses the wire being formed of any suitable alloy (Col. 3, lines 42 – 47). However, Cornish et al. fails to disclose the alloy being a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight. Herms et al. discloses a medical device for inserting into body passageways during medical procedures including a titanium molybdenum alloy wire having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight (Col. 4, lines 27 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the wire as disclosed by Cornish et al. to be formed of a titanium molybdenum alloy as taught by Herms et al. because the titanium molybdenum alloy has about three times as much elasticity as other possible alloys and thus helps to avoid unwanted permanent deformation (Col. 6, lines 3 – 6).

Response to Arguments

Applicant's arguments filed 3/8/04 have been fully considered but they are not persuasive.

In reference to the 35 U.S.C 103(a) rejections of U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent Application Publication No. 2003/0009215 to Mayer, Applicant has asserted that the examiner has not made out a *Prima Facie* case of obviousness. To support this assertion,

applicant has pointed to MPEP 2134 discussing the basic requirements of a *Prima Facie* Case of Obviousness and MPEP 2141.01(a) related to analogous and nonanalogous art.

As applicant has pointed out MPEP 2134 discusses three basic criteria that must be met in order to properly establish a *Prima Facie* case of obviousness. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicant has asserted that the examiner has erred in rejecting the claims and that all three of the basic criteria are not properly met in the rejection.

To begin, Applicant has cited MPEP 2141.01(a) related to analogous and nonanalogous art in support of the position that guidewires and stents are nonanalogous art. Applicant asserts that the motivation to combine the teachings of Mayer with Cornish et al. as a result to avoid undue irritation in patients having a sensitivity to nickel is a false statement since there is no problem with sensitivity to nickel in guidewires. Applicant continues by stating that guidewires remain in the body for a matter of a few minutes as opposed to stents which are meant for permanent installation. Applicant also states that a person skilled in the art of guidewires knows that guidewires are coated such that the alloy of the guidewire itself does not contact with the patient. Applicant's position is that the examiner has "made up a nonexistent issue" for combining the teachings of Mayer and Cornish et al.

The examiner disagrees. As applicant has pointed out, "[i]n order to rely on a reference as a basis for rejection of an applicant's invention, there reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which

the inventor was concerned." Additionally, "[a] reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem". In the present case, the examiner feels that guidewires and stents are analogous art in that they both are medical devices that are inserted into body lumens. Furthermore, it logically follows that an inventor of a guidewire to be inserted into a body lumen would be concerned with advancements made in any device inserted into a body lumen to overcome problems associated with allergic reactions while being placed within the body. Additionally, guidewires are commonly used during the placement of stents in the body. It would be counterproductive to have a hypoallergenic stent being placed in position by a guidewire that would lead to an allergic reaction which the stent was designed to avoid. Reactions to nickel are known to occur with only "brief contact with nickel-containing items" (http://www.dermnetnz.org/dna.nckel.allergy/info.html). Cornish et al. necessitates the alloy forming the guidewire being "sufficiently biocompatible" (Col. 3, lines 42 – 47). It seems unlikely that sensitivity is "definitely not an issue", as Applicant has asserted, when Cornish et al. requires the alloy being biocompatible. Cornish et al. further states that a coating covering the wire may "optionally be used" (Col. 3, lines 50 – 57). In the instance where such a coating is not used, the alloy of the wire would in fact contact the patient.

The Applicant has asserted that the reason to look to another art for a solution to a problem has to be for solving a problem the Applicant has identified in his application. However, this is not the case. It is not a requirement that in order to form a *Prima Facie* case of obviousness that the problem identified in an Applicant's application be the same as the problem solved by a reference (or references) in an obviousness rejection. "It is not necessary in order to establish a *Prima Facie* case of obviousness...that there be a suggestion or expectation from the prior art that the claimed

[invention] will have the same or a similar utility as one newly discovered by the applicant". ***In re Dillon***, 919 F.2d 688, 692, 16 USPQ2d 1897, 1900 (Fed. Cir 1990). Thus, "[i]t is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by Applicant." MPEP 2144 ("Rationale Different from Applicant's is Permissible"). It is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason (i.e. flexibility, softness, pushability, properties of kinking, springiness, torque transmission, etc.) as the applicant to make the claimed invention. In the present case, the motivation to combine comes from Mayer. Mayer suggests the inclusion of the claimed alloy in order to avoid undue irritation to patients having a sensitivity to nickel [0079]. The suggested combination of Cornish et al. in view of Mayer is a result of this teaching. Mayer suggests a combination based on the hypoallergenic properties of the titanium molybdenum alloy, not on the flexibility, softness, pushability, properties of kinking, springiness, torque transmission, bendability, memory, or stress and strain of the material.

In reference to the second test for establishing a *Prima Facie* case of obviousness, the combination of Cornish et al. in view of Mayer would lead to a reasonable expectation of success. It is a reasonable conclusion that the guidewire of Cornish et al., when formed of a titanium molybdenum alloy as taught by Mayer, would avoid undue irritation to patients having a sensitivity to nickel in that nickel would no longer be present in the titanium alloy.

In reference to the third test for establishing a *Prima Facie* case of obviousness, the combination of Cornish et al. in view of Mayer teaches or suggests all of the claim limitations (See above rejection).

Because the Examiner has shown that the basic requirements of a *Prima Facie* case of obviousness as required by MPEP 2143 have been satisfied, the rejection of the claims as

unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent Application Publication No. 2003/0009215 to Mayer is proper.

Additionally, Applicant has asserted that ***In re Leshin***, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) has been misapplied. However, the examiner disagrees. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In essence, Applicant's statement that "[n]or is there a design consideration involved with a simple substitution of materials as in *In re Leshin*" is contrary to this summation. The titanium molybdenum alloy is well known and has proven use within the medical community. As Cornish et al. discloses, any material is suitable for the core as long as the material is biocompatible and has the approximate mechanical properties of stainless steel and nickel titanium (Col. 3, lines 42 – 47). Since the claimed titanium molybdenum alloy is well known, and the properties of the alloy are well known as being approximate that of stainless steel and nickel titanium, a simple substitution of one alloy for another would in fact be an obvious design choice.

The Examiner would like to point out that Applicant's arguments were directed to a "titanium, molybdenum, zinc and tin alloy". However, the claims are directed to a titanium, molybdenum, zirconium and tin alloy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization

where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JMLF
March 19, 2004

Mary Beth Jones
Acting SPE
Art Unit 3736